

PESTICIDE PRODUCT REGISTRATION REFORM INITIATIVE

February 21, 2007

(Updated from September 10, 2004)

Goals of the Registration Reform Initiative

- Shorten the time frame for registration decisions.
- Eliminate unnecessary workload and costs for registrants and the Department of Pesticide Regulation (DPR).
- Expedite the introduction of lower-risk pesticides.
- Eliminate activities unrelated to protection of public health and the environment.

Results of the Registration Reform Initiative

California's pesticide product registration process serves to assure that pesticides sold in California are effective and will not pose unacceptable risks to public health or the environment. Some registration processes established via statute, regulation, and policy were designed to address issues that were inadequately managed by the U.S. Environmental Protection Agency (U.S. EPA). Over the past decade, many positive changes have occurred at U.S. EPA, which allow DPR to reexamine how it conducts pesticide registration. DPR's goal is to ensure timely decisions while enhancing protection of people and the environment.

Improvements in DPR's business processes will reduce delays in registration decisions and improve the timeliness of registration reviews.

Consultative Process

On March 26, 2004, DPR released the first draft of the Registration Initiative for discussion. It was discussed at the March 26 meeting of the Pest Management Advisory Committee. Committee members and other participants offered suggestions for improvements to the initiative, as well as further actions DPR should take in response to those suggestions. DPR released a revised draft on April 30. The initiative was also discussed at the May 21 meeting of the Pesticide Registration and Evaluation Committee. DPR also received comments from various organizations. The comments are posted on DPR's Web site at <http://www.cdpr.ca.gov/docs/planning/planning.htm>.

Implemented Reforms

Accept U.S. EPA Reviews – On June 16, 2004, DPR issued a Notice to Registrants encouraging them to provide DPR with copies of U.S. EPA's data evaluation reports (DERs) when they submit scientific data. Under this policy, whenever DPR receives copies of U. S. EPA DERs, DPR will review the reports and only review the underlying data on an as needed basis. This

should reduce evaluation time, since less time is needed to review only the U.S. EPA evaluation reports. Unfortunately, only some registration requests will benefit from this policy because U.S. EPA produces formal reviews for only a portion of the products that it registers.

Residue Data – DPR, by policy, no longer requires applicants for registration of new food-use pesticide products, and applicants to amend a currently registered pesticide product to add a new food use, to automatically submit residue data to DPR. DPR retains its authority to require an applicant to submit residue data on a case-by-case basis, either during evaluation or after registration.

Registration Status e-Notification – DPR currently provides electronic updates to registrants on the status of their registration requests. The e-notification provides registrants with better and timelier information on the status of applications, and reduces the time DPR staff spend answering queries from registrants. The information provided by this system allows the registrants to resolve registration review issues expeditiously and to better gauge when their products will be available for the California market.

Repeal of California Data Ownership Laws - Assembly Bill 1011 (AB 1011, Chapter 612, Statutes of 2005) amended Food and Agricultural Code (FAC) section 12811.5, allowing the Department to rely upon any evaluation of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered pesticide product, or to maintain the registration of a pesticide product, regardless of the ownership of the data previously evaluated. The new statute did not change or reduce the data requirements for California registration, but eliminated the Department's involvement in compensation. The new law is reducing the number of products that require the submission of scientific data, and therefore, the number of products requiring scientific evaluation, including efficacy data evaluation. As a result of AB 1011, in June 2006, DPR withdrew its proposed regulation change regarding efficacy data requirements for pesticide products (DPR Regulation Notice 05-002). AB 1011 is expected to significantly reduce the need for an applicant to conduct and submit efficacy data. The new statute also allows for concurrent submission of all new active ingredient applications with submission to the U.S. EPA.

Enhancing Work Share Opportunities - The Department continues to enhance its work share opportunities with the U.S. EPA through its ongoing effort to review IR-4 specialty crop residue data, participation in the Global Harmonization System workgroup, and by providing open communication. DPR continues to work closely with the U.S. EPA as it redesigns its pesticide registration process, providing new opportunities to share the registration workload and minimize time frames for California registration requests, while continuing to address both human and environmental concerns.

Section 18 Process and Procedure Revisions - Critical pest infestations are sometimes handled through processes other than the routine pesticide product registration system. The emergency exemption process (Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 18) and Special Local Needs (FIFRA section 24c) are two key processes that are critical to unique situations. These avenues to address pest management needs involve both federal and state authorities.

In 2006, U.S. EPA revised its FIFRA section 18 guidelines in an effort to streamline the application process and put forth more defined guidelines in order to provide greater consistency and more expeditious review for the applicant. Key components, including development of a tiered system defining significant economic loss and outlining strict guidelines identifying when an emergency condition is warranted, were added. The Department plans to continue to explore ways in which the U.S. EPA and DPR can further improve this process.

Planned Reforms

Analysis of Organic Agriculture - As part of a nationwide effort to meet the increasing demand for organic production pesticides, DPR continues to examine how it might remove any barriers to the registration of pesticide products needed by California organic growers. DPR is in the process of analyzing the registration process at U.S. EPA for products that qualify for use on organic crops, and exploring registration options in California. Currently, DPR accepts concurrent applications for registration of organic products containing new active ingredients.

California Conditions – DPR plans to issue a notice clarifying environmental field dissipation data requirements for applicants for registration of the first agricultural use of an active ingredient. FAC section 13143 requires registrants to conduct two field dissipation studies, and DPR has required at least one to be conducted under California or similar use conditions. DPR is developing criteria that could be used to qualify a dissipation study conducted in another state as having been conducted under “California or similar environmental conditions.” In most instances, the same studies that the registrant submits to U.S. EPA will fulfill California requirements. The policy change will not affect DPR’s scientific determination of whether an active ingredient is likely to move into ground water.

ACCOUNTABILITY

Beginning January 1, 2005, DPR will issue a biannual report on the status of the pesticide product registration reform initiatives, the performance of the registration process, current allocation of resources, and any improvements resulting from the initiative.

REFERENCES

Challenge and Change (1991)
Western Crop Protection Association (1995)
New Point Report (2001)
AB 780 Report (2003)